IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

JIHAN DARWISH, Plaintiff, v. ETHICON INC., d/b/a ETHICON WOMEN'S HEALTH AND UROLOGY, a Division of Ethicon Inc., GYNECARE WORLDWIDE, and JOHNSON & JOHNSON, Defendants.	)	Case No.

COMPLAINT

NOW COMES the Plaintiff, JIHAN DARWISH, by and through her attorneys, Cutter Law, PC, and complains of the Defendants, ETHICON, INC. d/b/a ETHICON WOMEN'S HEALTH AND UROLOGY, a Division of Ethicon, Inc., GYNECARE WORLDWIDE, and JOHNSON & JOHNSON (collectively "Defendants"), upon information and belief and states as follows:

NATURE OF THE ACTION

1. Plaintiff Jihan Darwish bring this case against Defendants for the injuries incurred from the implantation of a medical device that was negligently manufactured and designed by the Defendants and failed to contain appropriate and significant warnings related to its use.

THE PARTIES

2. Plaintiff Jihan Darwish ("Ms. Darwish" or "Plaintiff") is a citizen and resident of the County of Cuyahoga, in the State of Ohio.
3. Defendant Johnson & Johnson ("Johnson & Johnson") is a New Jersey Corporation with its worldwide headquarters and principal place of business located at One Johnson &

Johnson Plaza, New Brunswick, New Jersey. Johnson & Johnson is a citizen and resident of New Jersey.

4. Defendant Ethicon, Inc. d/b/a Ethicon Women's Health and Urology ("Ethicon") is a New Jersey Corporation with its principal place of business in Somerville, New Jersey. Ethicon is a citizen and resident of New Jersey. All acts and omissions of Ethicon as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership. Ethicon is a subsidiary of Johnson & Johnson.
5. Defendant Gynecare Worldwide ("Gynecare Worldwide"), a division of Ethicon, Inc., is a New Jersey Corporation with its principal place of business in Somerville, New Jersey. Defendant Gynecare is a citizen and resident of New Jersey.

JURISDICTION AND VENUE

6. Plaintiff brings this complaint under federal diversity jurisdiction, 28 U.S.C. § 1332, as the parties are completely diverse in citizenship and the amount in controversy exceeds $75,000.
7. Venue is proper under 28 U.S.C. § 1391(b) as a substantial part of the events giving rise to this claim occurred in this district and the Plaintiff resides in this district.

FACTUAL ALLEGATIONS

8. Plaintiff was implanted with a Gynecare TVT Mesh product during surgery performed at the Cleveland Clinic/Lakewood Hospital in Lakewood, Ohio on September 26, 2011.
9. Plaintiff was implanted with a Gynecare TVT ABBREVO Mesh Model no. TVTOML.
10. Defendants, at all times material hereto, manufactured the Gynecare TVT Mesh products.

11. Defendants, at all times material hereto, manufactured the Gynecare TVT Abbrevo Mesh product, Device No. TVTOML.
12. The Gynecare TVT Abbrevo Mesh product was implanted in the Plaintiff to treat her for Stress Urinary Incontinence and other symptoms, the use for which the product was designed, marketed and sold.
13. Stress Urinary Incontinence is a type of disorder by which urine leaks during physical movement or activity, such as coughing or sneezing.
14. This product contains a monofilament polypropylene mesh intended to treat Stress Urinary Incontinence.
15. As a result of having the Gynecare TVT Abbrevo Mesh product implanted in her, Plaintiff has experienced significant mental and physical pain, disability, suffering, has sustained permanent injury, and permanent and substantial physical deformity, has suffered financial or economic loss, including, but not limited to obligations for medical services and expenses, lost income, has endured impaired physical relations with her husband, and other damages.
16. Plaintiff (Ms. Darwish) was hospitalized and on April 20, 2018 and underwent a procedure in which mesh was removed due to pain and complications with the TVT Abbrevo Mesh.
17. Plaintiff's injuries would not have occurred but for the defective nature of the products implanted and/or Defendants' wrongful conduct.
18. Defendants at all times material hereto, was engaged in the business of placing medical devices in the stream of commerce by designing, manufacturing, marketing, packaging, labeling, and selling such devices, including the Gynecare TVT Abbrevo Mesh product that was implanted in the Plaintiff, which gives rise to the Plaintiff's claims asserted herein.

19. Defendants at all times material hereto designed the Gynecare TVT Abbrevo Mesh products, including that which was implanted in the Plaintiff, which gives rise to the Plaintiff's claims asserted herein.

20. Defendants at all times material hereto manufactured the Gynecare TVT Mesh products, including that which was implanted in the Plaintiff, which gives rise to the Plaintiff's claims asserted herein.

21. Defendants at all times material hereto marketed the Gynecare TVT Mesh products through television, print and internet advertising and by sending sales representatives throughout the United States and to the State of Ohio to promote the sale of the Gynecare TVT Mesh products, including that which was implanted in the Plaintiff.

22. Defendants at all times material hereto packaged the Gynecare TVT Mesh products, including that which was implanted in the Plaintiff.

23. Defendants at all times material hereto labeled the Gynecare TVT Mesh products by placing its name on the outside of the Gynecare TVT Mesh's packaging.

24. Defendants at all times material hereto, sold the Gynecare TVT Mesh products throughout the United States, including the State of Ohio.

25. In October 2008 and July 2011, the Food and Drug Administration ("FDA") issued warnings regarding the complications and risks associated with Pelvic Mesh Products, including the TVT Abbrevo Mesh.

26. Defendants knew or should have known that the TVT Abbrevo Mesh unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks.

27. Despite claims that polypropylene mesh is inert, the scientific evidence shows that this material as implanted in Plaintiff is biologically incompatible with human tissue and when used as a woven or knitted alloplastic textile prosthetic mesh for pelvic floor repair, polypropylene and other surgical polymers promote a severe foreign body reaction and chronic inflammatory response in a large subset of the population implanted with Defendants' pelvic mesh products, including the TVT Abbrevo Mesh.

28. The Product was unreasonably susceptible to degradation and fragmentation inside the body; shrinkage or contraction inside the body; intense foreign body reaction; chronic inflammatory response; chronic wound healing; chronic infections in and around the mesh fibers; nerve entrapment in the collagen scar formation. Defendants knew or should have known of these serious risks and should have, therefore, warned physicians and patients regarding these risks; to the extent they were known or knowable.

29. Defendants omitted and downplayed the risks, dangers, defects, and disadvantages of the TVT Abbrevo Mesh product, and advertised, promoted, marketed, sold and distributed the TVT Mesh products as safe medical devices when Defendants knew or should have known that the TVT Abbrevo Mesh product was not safe for its intended purposes, and that the TVT Mesh products would cause, and did cause, serious medical problems, and in some patients, including Plaintiff, catastrophic injuries. Further, while some of the problems associated with the TVT Abbrevo Mesh product was made known to physicians, the magnitude and frequency of these problems were not disclosed and were hidden from physicians.

30. Contrary to Defendants' representations and marketing to the medical community and to the patients themselves, the TVT Abbrevo Mesh product has high rates of failure, injury, and complications, fails to perform as intended, requires frequent and often debilitating

re-operations, and has caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiff, making them defective under the law.

31. The specific nature of the TVT Abbrevo Mesh ("the Product")'s defects includes, but is not limited to, the following:

    a. The use of polypropylene in the Product and the adverse tissue reactions and host defense response that result from such material, causing adverse reactions and serious, permanent injuries including, but not limited to, painful recurrent erosions, painful infections and associated intractable pain;

    b. The design of the Product to be inserted into and through an area of the body that is blood vessel rich, nerve dense, and bacteria laden leading to excessive blood loss and vascular damage, permanent nerve injury and associated chronic, intractable neuropathic pain, contaminated permanently-implanted mesh causing chronic infections, subclinical infections and biofilms, enhanced chronic inflammatory response, chronic wound healing with tissue destruction, as well as numerous other adverse reactions and serious and permanent injuries;

    c. Biomechanical issues with the design of the Product which result in a non-anatomic condition leading to contraction or shrinkage of the mesh inside the body, that in turn causes surrounding tissue to become eroded, inflamed, fibrotic and infected, resulting in serious and permanent injury;

    d. The propensity of the mesh design characteristics of the Product for plastic deformation when subjected to tension both during implantation and once implanted inside the body which causes the mesh, or portions thereof, to be encapsulated in a rigid scar plate which leads to nerve entrapment, bacterial

entrapment, tissue destruction, enhanced inflammatory and fibrotic response and chronic pain;

e. The propensity of the Product to become rigid and inflexible, causing them to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where they are implanted, and causing discomfort and pain with normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking);

f. The propensity of the Product for degradation or fragmentation over time, which causes an increased surface area that leads to enhanced chronic inflammatory and fibrotic reaction, causes a "barbed wire" or "saw blade" effect by the fragmented surface "sawing" through the tissue, leads to bacteria harboring in the fragmented, peeled and split fiber surface which in turn leads to chronic infections at the mesh surface, and results in continuing injury over time; and

g. The inability of surgeons to effectively treat many of these conditions due to the integration of the mesh into the pelvic tissue and thus the inability to safely remove or excise the mesh once a complication occurs.

32. The Product is also defective due to Defendants' failure to adequately warn or instruct Plaintiff and/or her health care providers of subjects including, but not limited to, the following:

a. The Product's propensities to contract, retract, and/or shrink inside the body;

b. The Product's propensities for degradation, fragmentation and/or migration;

c. The Product's inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. The frequency and manner of transvaginal mesh erosion or extrusion;

e. The risk of chronic inflammation resulting from the Product;

f. The risk of chronic infections resulting from the Product;

g. The risk of permanent vaginal or pelvic scarring as a result of the Product;

h. The risk of de novo urinary dysfunction;

i. The risk of de novo dyspareunia or painful sexual relations;

j. The risk of recurrent, intractable pelvic pain and other pain resulting from the Product;

k. The need for corrective or revision surgery to adjust or remove the Product which in some cases is not feasible nor possible;

l. The severity of complications that could arise as a result of implantation of the Product;

m. The hazards associated with the Product;

n. The Product's defects described herein;

o. Treatment of Stress Urinary Incontinence with the Products is no more effective than feasible, available and safer alternatives;

p. Treatment of Stress Urinary Incontinence with the Product exposes patients to greater risk than feasible, available and safer alternatives;

q. Treatment of Stress Urinary Incontinence with the Product makes future surgical repair more difficult than feasible, available and safer alternatives;

r. Use of the Product puts the patient at greater risk of requiring additional surgery than feasible, available and safer alternatives;

s. Removal of the Product due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

t. Complete removal of the Product may not be possible and may not result in complete resolution of the complications, including pain; and

33. The Product implanted in Plaintiff was in the same or substantially similar condition as they were when they left Defendants' possession, and in the condition directed by and expected by Defendants.

CAUSES OF ACTION AGAINST ALL DEFENDANTS

COUNT I
NEGLIGENCE

34. Plaintiff incorporates by reference paragraph 1-33 of this Complaint as if fully set forth herein.

35. Defendants had a duty to individuals, including Plaintiff, to use reasonable care in designing, manufacturing, marketing, labeling, packaging and selling the Gynecare TVT Abbrevo Mesh.

36. Defendants were negligent in failing to use reasonable care in designing, manufacturing, marketing, labeling, packaging, and selling the Gynecare TVT Abbrevo Mesh.

37. As a direct and proximate result of Defendants' negligence, Plaintiff was caused and/or in the future will be caused to suffer severe personal injuries, pain, disability and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

WHEREFORE, Plaintiff demands judgment against the Defendants for compensatory, treble and punitive damages, including costs and attorney's fees, and all such other relief as the Court may deem proper.

COUNT II
STRICT LIABILITY – DESIGN DEFECT
(ORC §2307.75, *et seq.*)

38. Plaintiff incorporates by reference paragraphs 1-37 of this Complaint as if fully set forth herein.

39. The Gynecare TVT Abbrevo Mesh product implanted in the Plaintiff was not reasonably safe for its intended use and was defective as a matter of law with respect to its design.

40. As a direct and proximate result of the Gynecare TVT Abbrevo Mesh's aforementioned defects, Plaintiff was caused and/or in the future will be caused to suffer severe personal injuries, pain, disability and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligation for medical services and expenses, lost income, and other damages.

41. Defendants are strictly liable to Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

Wherefore, Plaintiff demands judgment against the Defendants for compensatory, treble and punitive damages, including costs and attorney's fees, and all such other relief as the Court may deem proper.

COUNT III
STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT
(ORC §2307.74, *et seq.*)

42. Plaintiff incorporate by reference paragraphs 1- 41 of this Complaint as if fully set forth herein.

43. The Gynecare TVT Abbrevo Mesh product implanted in the Plaintiff was not reasonably safe for its intended use and was defective as a matter of law with respect to its manufacture.

44. As a direct and proximate result of the Gynecare TVT Mesh's aforementioned defects, Plaintiff was caused and/or in the future will be caused to suffer severe personal injuries, pain, disability, suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

Wherefore, Plaintiff demands judgment against the Defendants for compensatory, treble and punitive damages, including costs and attorney's fees, and all such other relief as the Court may deem proper.

COUNT IV
STRICT LIABILITY – FAILURE TO WARN
(ORC §2307.76, *et seq.*)

45. Plaintiff incorporates by reference paragraphs 1- 44 of this Complaint as if fully set forth herein.

46. The Gynecare TVT Abbrevo Mesh product implanted in the Plaintiff was not reasonably safe for its intended use and was defective as a matter of law due to its lack of appropriate necessary warnings.

47. As a direct and proximate result of the Gynecare TVT Abbrevo Mesh's aforementioned defects, Plaintiff was caused and/or in the future will be caused to suffer severe personal injuries, pain, disability, suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

WHEREFORE, Plaintiff demands judgment against the Defendants for compensatory, treble and punitive damages, including costs and attorney's fees, and all such other relief as the Court may deem proper.

COUNT V
Strict Product Liability: Defect Due to Nonconformance with Representation
(ORC §2307.75, *et seq.*)

48. Plaintiff incorporates by reference paragraph 1- 47 of this Complaint as if fully set forth herein.

49. Defendants expected and intended the TVT Abbrevo mesh product to reach users such as Plaintiff in the condition in which the product was sold.

50. Defendants represented to Plaintiff and/or her implanting physician that the TVT Abbrevo mesh was safe and effective. At the time her implanting physician chose the TVT Abbrevo mesh for implantation in Plaintiff, he reasonably and justifiably relied upon Defendants' representations that the product was safe for use for the repair of Stress Urinary Incontinence and would conform to Defendants' representations regarding the character and quality of the TVT Abbrevo mesh for use.

51. As a direct and proximate result of Plaintiff's and/or her physician's reliance on Defendant's representations about the TVT Abbrevo mesh, Plaintiff suffered injuries and damages as summarized herein.

WHEREFORE, Plaintiff demands judgment against the Defendants for compensatory, treble and punitive damages, including costs and attorney's fees, and all such other relief as the Court may deem proper.

TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

52. Plaintiff by reference paragraphs 1-51 of this Complaint as if fully set forth herein.

53. Plaintiffs assert all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including, equitable

tolling, class action tolling, delayed discovery, discovery rule, and Ohio's H.B.197, which extended any applicable statute of limitations until July 30, 2020.

JURY DEMAND

Plaintiff demands a jury trial on all counts.

Date:

Respectfully Submitted,

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